REMARKS

Entry of the foregoing and further and favorable consideration of the subject application are respectfully requested.

Claims 1-30 are pending in the present application. Claims 11-17 and 19-30 stand withdrawn from consideration. Claims 1-10 and 18 stand rejected.

By the present amendment, new claims 31-35 have been added. Support for new claims 31-35 can be found, at least, in claims 1-10 and 18 as originally filed. No new matter has been added. Moreover, Applicants respectfully submit that new claims 31-35 fall within Group I, which has been previously elected in response to the restriction requirement, mailed June 13, 2002 (Paper No. 8).

Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1-10 and 18 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. The Examiner argues that the claims are directed toward peptides which have not been described as there are an "inordinate" number of substitutions permitted in the peptide. The Examiner asserts that the disclosure does not describe the preparation of a reasonable number of peptidic species or the molecular determinants modulating the antiviral properties of the various compounds. The Examiner concludes that Applicants are attempting to claim more subject matter than to which they are entitled. This rejection, as it applies to the present claims, and to the extent that it may apply to new claims 31-35, is respectfully traversed.

Initially, Applicants respectfully submit that, at the very least, Claim 10 should not have been included in this rejection as this claim recites a particular sequence wherein all positions are defined. Thus, the Examiner's arguments cannot apply to this claim.

As claim 1 is the broadest claim under rejection, Applicants address the rejection in terms of this claim. Claim 1 is directed to a peptide or analog comprising a decapeptide that contains (from N-terminus to C-terminus), a basic amino acid at position 1, an acidic amino acid at positions 2 and 5, and a tryptophan in positions 4, 7, and 8.

The Federal Circuit has recently reiterated that "[t]he purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to 'recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 2003 U.S. App. LEXIS 118, p. 35 (Fed. Cir. Jan. 6, 2003), citing *Vas-Cath Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1115 (Fed. Cir. 1991). A copy of the *Hoechst* decision is enclosed for the Examiner's convenience. A determination of whether this requirement is satisfied is necessarily measured by "the understanding of the ordinarily skilled artisan." *Hoechst*, at p. 35 citing *Lockwood v. Am. Airlines, Inc.*, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997).

The Examiner has cited a number of recent cases concerning the written description standards for nucleotidic or peptidic species. Particularly, the Examiner cites *Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 U.S.P.Q.2d 1016-1031 (Fed. Cir. 1991). *Amgen* stood for the proposition that a gene is sufficiently complex that an inventor must be able to envision the detailed constitution so as to distinguish the gene from another species.

Amgen, 18 U.S.P.Q.2d at 1021. However, *Amgen* and the other cases cited by the Examiner are inapposite to the presently claimed invention. The inventors in *Amgen* were attempting to claim nucleotide sequences encoding a 34 kDa protein without defining any part of the nucleotide sequence itself. *Amgen*, 18 U.S.P.Q.2d at 1019. The presently claimed invention is not directed to an entire gene or protein defined solely by the function of the protein, but rather encompasses decapeptides that contain a particular motif that has been identified as inhibitory towards HIV reverse transcriptase. Thus, in contrast to *Amgen* and related cases, the relevant structural features are disclosed in the present claims.

Applicants submit herewith the declaration of Dr. Gilles Divita, Ph.D., an inventor of the present application, that provides further confirmation that Applicants have indeed identified the critical residues in the presently claimed invention. Dr. Divita states that the data in Table 1 of the specification support the identification of conserved amino acids which are responsible for the reverse transcriptase inhibitory ability of the claimed decapeptide. Dr. Divita attests to the unimportance of the identity of the amino acid residue in position 9, which was shown to be highly variable in Table 1 of the specification. Dr. Divita has also conducted additional tests, described in his Declaration, that confirm the importance of the tryptophan residues at positions 4, 7, and 8 and the basic amino acid at position 1 to the reverse transcriptase inhibitory ability. When these residues are altered, the reverse transcriptase inhibition is dramatically reduced. These results reinforce the disclosure in the present specification that certain conserved amino acid residues are critical to the inhibitory activity of the decapeptide.

The Examiner incorrectly asserts that "the disclosure fails to provide a detailed description of the molecular determinants modulating the antiviral properties of these various compounds." Contrary to the Examiner's position, the present inventors have identified the relevant molecular determinants of the decapeptides - Table 1 of the instant specification clearly identifies the conserved motif of an inhibitory peptide sequence across a number of HIV strains. Conservation of a motif across various species is the hallmark of evolutionary importance. Table 1 exemplifies over 15 different sequences bearing this motif. This motif is distinctly claimed in claim 1. It is apparent from the application that the present inventors (and evolution) deem the choice of the other amino acids of the decapeptides as less critical. It is only certain amino acids in the decapeptides that dictate the inhibitory activity. Thus, claim 1 clearly describes the invention. All other information to be filled in is readily supplied by one skilled in the art. This is in keeping with the purpose of the written description requirement as stated by the Federal Circuit in *Hoechst* and *Vas-Cath*.

The Examiner has argued that a "reasonable number" of peptides has not been described in the specification. However, the Examiner has not provided any scientific evidence as to why the number of exemplary sequences found in the specification is insufficient to establish possession of the claimed invention. To the contrary, Applicants respectfully submit that the high degree of conservation of this motif across numerous HIV strains is strong evidence that the presently claimed invention has been adequately described.

While the number of peptides that fall within the scope of independent claim 1 is admittedly large, it is also finite. First, the peptide itself is only 10 amino acids in length. Second, claim 1, the broadest claim, defines 6 of the 10 amino acid residues, with a slight degree of "wobble" at 3 of those 6 positions. New independent claim 31 defines all 10 positions, with a slight degree of "wobble" at 7 of the 10 positions. Third, there are a limited number of known amino acids. Fourth, Applicants respectfully submit that one of ordinary skill in the art could readily list all possible sequences of the claimed decapeptide based on the information provided in the specification and claims, given the finite length and amino acids known to those skilled in the art. Applicants respectfully submit that this could still be done in the present specification, should the Examiner deem it necessary, without introducing new matter, given the finite number of possibilities and the limited number of known amino acids. Applicants express their willingness to do so, should the Examiner request that Applicants conduct such an exercise. However, this is believed to be unnecessary given the purpose of the written description requirement as discussed above and the requirement that the invention be described in clear and concise terms. *See* 35 U.S.C. § 112, first paragraph. In light of the "understanding of the ordinarily skilled artisan," there can be no doubt that the claims adequately identify the features of the invention such that the skilled artisan would be able to readily identify whether a particular decapeptide was encompassed by the claimed invention.

Importantly, the cases cited by the Examiner which encompassed as-yet undiscovered genes. In contrast, all sequences falling within the scope of the claims are adequately described in the specification by their length, the identity of the important amino

acid residues, and their function, which the present application and the accompanying Declaration of Dr. Divita have shown to be intimately tied to the important amino acid residues identified.

Applicants respectfully point out that the Examiner has not provided any evidence that any peptides falling within the scope of the claims would be inoperative. Applicants respectfully submit that there is not reason to believe that any peptides of the presently claimed invention will not possess the reverse transcriptase activity. Moreover, the means to ascertain the function of a given decapeptide as an inhibitor of HIV reverse transcriptase is within the ordinary skill of the artisan, based techniques already known in the art and exemplified in the specification. Creation of any decapeptide within the scope of the claims is equally routine, as peptide synthesis is well-known in the art.

Thus, Applicants respectfully submit that the decapeptides of the presently claimed invention are described by 1) their length, 2) their function, and 3) the identification of amino acid residues that contribute to the inhibition of reverse transcriptase. Applicants have identified important new inhibitors of reverse transcriptase based on a critical motif identified in the specification. Applicants respectfully submit that the present claims are adequately supported by the specification and the understanding of one skilled in the art. Applicants are not simply trying to claim "subject matter to which they are not entitled," as suggested by the Examiner, but rather only the full scope of their invention. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusions

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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